UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ERMARIS BIO, PBC, *Plaintiff*, -v- THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK, Defendant.	Civil Action No. _____ **COMPLAINT** **JURY TRIAL DEMANDED**

Ermaris Bio, PBC ("**Plaintiff**"), by and through its undersigned attorneys, files this Complaint against The Trustees of Columbia University in the City of New York ("**Columbia**"), as follows:

I. PRELIMINARY STATEMENT

1. On August 17, 2023, Dr. Kevin McLure incorporated Plaintiff, a biotechnology company, with a singular goal—to develop a best-in-class oral medication to treat retinal diseases that cause blindness.

2. A few months later, on November 24, 2023, Plaintiff and Columbia entered into an Option Agreement (the "**Agreement**") in which Columbia granted Plaintiff an option to negotiate with Columbia in good faith for a license to patents relating to the (R)-44 molecule.[1]

3. Under the terms of the Agreement, Plaintiff had a year to secure $3 million in financing and nine-months to submit a complete business plan that would be acceptable to Columbia. Under this provision, Columbia was required to assess the business plan in good faith

[1] (R)-44 is known by a number of different names including (R)-ACPHS-62 or (R)-50 (when used by Columbia), SMP-110 (in connection with SciMount's license which is discussed below), and ERM-001 and ERM-123 (both in connection with the Agreement).

while acting reasonably.

4. If these conditions were met, Columbia was obligated to negotiate with Plaintiff in good faith to enter into a licensing agreement.

5. About nine months later, on August 16, 2024, Plaintiff presented a feasible business plan to Columbia and exercised its option for a three-month extension to raise capital.

6. Columbia, however, reneged on the Agreement in bad faith because Columbia received a grant from the National Institutes of Health ("**NIH**"), which Columbia wanted to use to conduct the studies itself and, upon information and belief, eliminate competition from Plaintiff, who would be significantly ahead in developing the (R)-44 molecule once Plaintiff raised capital.

7. As a result of Columbia's breach, Plaintiff has suffered substantial damage.

8. Columbia's breach has prevented Plaintiff from securing the licenses needed to proceed with drug development, effectively destroying Plaintiff's business plan for developing a drug in a $20 billion market.

9. Moreover, Plaintiff has spent roughly a year on fundraising and other business development activities, at considerable expense.

10. Plaintiff now seeks to be made whole, putting it in the same financial position as it would have been absent Columbia's breach.

II. PARTIES

11. Plaintiff is a biotechnology corporation incorporated under the laws of the State of Delaware with its principal place of business in Newton Center, Massachusetts. Plaintiff is incorporated as a public benefit corporation, meaning that while Plaintiff is a for-profit entity, it is legally obligated to balance profit with a social mission.

12. Defendant The Trustees of Columbia University in the City of New York is the legal name of Columbia University, a private not-for-profit university based in and incorporated under the laws of New York.

III. JURISDICTION AND VENUE

13. Subject matter jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332 because the parties are citizens of different States and the amount in controversy exceeds $75,000.00.

14. This Court has personal jurisdiction over Columbia pursuant to N.Y. C.P.L.R 301 because, upon information and belief, Columbia is domiciled and/or incorporated in New York.

15. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims in this lawsuit arose in this district and Columbia is subject to the Court's personal jurisdiction in this district.

IV. FACTUAL ALLEGATIONS

A. Dr. McLure Incorporates Plaintiff To Continue The Development Of A Potentially Life-Changing Medication.

16. Dr. McLure is the CEO and founder of Plaintiff, which was conceived and incorporated in 2023 with the goal of developing a best-in-class oral drug to treat retinal diseases causing blindness.

17. Plaintiff's incorporation came on the heels of Dr. McLure's prior consulting work for SciMount Therapeutics ("**SciMount**"), a drug development company which is a division of Xiling Labs.

18. Dr. McLure consulted for SciMount from 2020 to 2023, via an entity he created

called Ermaris Bio Inc.[2]

19. On June 30, 2021, SciMount entered into a licensing agreement with Columbia for rights to a patent owned by Columbia, covering molecules created at Columbia (US Provisional Application No. 63/054,218).

20. The licensing agreement between Columbia and SciMount authorized SciMount to develop molecules, including one referred to as (R)-44, to treat retinal diseases that cause blindness.

21. SciMount ran a series of experiments with the (R)-44 molecule that demonstrated that (R)-44 has the potential to treat people with diseases that cause blindness.

22. Thus, SciMount's experiments on (R)-44 generated positive, conclusive data.

23. The next step in development was to run tests on (R)-44 to ensure reliability for an "Investigational New Drug" ("**IND**") application to the Food and Drug Administration.

24. These tests are called IND-enabling preclinical studies.

25. IND-enabling studies must be conducted at specially qualified contract research organizations and are expensive, costing between $1 million and $3 million.

26. SciMount chose not to allocate capital to perform the IND-enabling preclinical studies.

27. As a result, SciMount agreed to return the rights to (R)-44 to Columbia so that Dr. McLure could independently pursue licensing and development of (R)-44.

28. Thus, Dr. McLure formed Plaintiff to continue the development of (R)-44, a potentially life-changing medication.

29. SciMount provided the preclinical results to Columbia, agreeing that Columbia

[2] Ermaris Bio Inc. is not affiliated with Plaintiff.

could share them with Plaintiff to assist Plaintiff in preparing pitch decks to raise capital from investors.

30. On May 19, 2023, Dr. McLure spoke with Dr. Konstantin Petrukhin, a professor at Columbia, about licensing the patent from Columbia covering (R)-44 to run studies relating to the (R)-44 molecule, independent of SciMount.[3]

31. On the heels of this conversation, on May 24, 2023, SciMount communicated, in writing, its positive results concerning the (R)-44 molecule to the Senior Technology Licensing Officer at Columbia Technology Ventures ("**CTV**"), Kristin Neuman ("**Neuman**"), and indicated the results had also been shared with Dr. Petrukhin.

32. CTV is part of Columbia University, and Dr. Petrukhin is a faculty member at Columbia and co-inventor of the licensed intellectual property, which included (R)-44.

33. On June 30, 2023, SciMount's licensing agreement with Columbia concluded.

34. In August 2023, Dr. McLure incorporated Plaintiff.

35. Dr. McLure knew that the next step to achieving his drug development goal would be to run the IND-enabling preclinical studies with the (R)-44 molecule.

36. Dr. McLure's preparation, therefore, hinged on contemporaneous negotiations with Columbia as he understood that his venture was impossible without a license to Columbia's patents that covered (R)-44.

B. Columbia And Plaintiff Enter Into The Agreement.

37. On November 24, 2023, Plaintiff entered into the Agreement with Columbia.[4]

38. Under the Agreement, Plaintiff obtained an exclusive option to negotiate with

[3] Dr. Petrukhin has been assisted in his research by Dr. Christopher Cioffi, currently a professor at Rensselaer Polytechnic Institute.

[4] The Agreement is attached as Exhibit 1, which is incorporated by reference.

Columbia in good faith for a license to patents relating to the (R)-44 molecule, including US Provisional Application No. 63/054,218.

39. As a condition-precedent to exercising the option, Plaintiff agreed that within nine months of signing the Agreement it would:

(a) provide Columbia with a business plan that would satisfy Columbia so long as Columbia acted "reasonably and in good faith;"

(b) satisfy any reasonable requests for information Columbia may have in performing due-diligence; and

(c) obtain any necessary internal and external approvals for transactions contemplated by the Agreement.

40. The parties further agreed that Plaintiff was to raise $3,000,000 in funding prior to the exercise of the option.

41. In the Agreement, Plaintiff retained the ability to invoke a three-month extension for the funding.

42. Thus, Plaintiff had one year to raise the necessary capital to exercise its option to negotiate a license agreement with Columbia.

43. Columbia, in turn, provided certain assurances to Plaintiff in the Agreement.

44. Most significantly, Columbia promised that upon Plaintiff's exercise of its option, Columbia would negotiate a licensing agreement in good faith.

45. Conspicuously absent from the Agreement was any mention of faculty research or any internal grant award that would thwart Columbia's performance of the Agreement.

46. Columbia also agreed to an exclusive negotiation provision, which stated that it would not negotiate, license, grant any option, or "directly or indirectly" commercialize the patents

at issue to any third-party other than a non-profit before the end of the option period.

C. Plaintiff Dedicates Time and Resources To Satisfy Its Obligations In The Agreement.

47. Over the next eight months, Plaintiff worked at great expense to satisfy its obligations under the Agreement and fulfill Plaintiff's mission of creating a once-a-day oral treatment for retinal diseases causing blindness.

48. Plaintiff obtained quotes from multiple research organizations that would have allowed it to complete the IND-enabling preclinical studies within just one year.

49. Plaintiff was also negotiating with SciMount to procure the Good Manufacturing Process ("**GMP**") grade (R)-44 drug substance that SciMount had already produced, which would be sufficient quality and amount needed to run both the IND-enabling preclinical studies and Phase I clinical studies. This would allow Plaintiff to accelerate its research by nearly one year.

50. Further, Plaintiff retained a chemistry manufacturing and controls specialist who evaluated the SciMount data to ensure the GMP material had been maintained properly and confirmed that it would be acceptable for use in the IND-enabling preclinical studies and the first phase of clinical studies.

D. Columbia Improperly Applies For An NIH Grant To Conduct Studies For (R)-44 Covered By The Agreement.

51. In or about the summer of 2023, Drs. Cioffi and Petrukhin, on behalf of Columbia, applied to the National Eye Institute ("**NEI**"), which is part of the NIH, for a grant to run the IND-enabling preclinical studies with the (R)-44 molecule.

52. On June 7, 2024, Columbia received grant funding from the NEI in the amount of $774,169, with $474,999 going to support Drs. Cioffi and Petrukhin's laboratories and the remaining $299,170 flowing to Columbia as indirect costs.[5]

[5] The funded Project Number is 1R61EY036287 ("**R61**").

53. Pursuant to the grant, if Drs. Cioffi and Petrukhin obtain positive results, following NEI panel review, they would unlock a second phase of funding.

54. Upon information and belief, in the second phase of funding, Columbia would receive a $5 million grant from NEI.

55. Upon information and belief, at the time Columbia reneged on the Agreement, Columbia would have anticipated receiving an additional 63% of the $5 million, or $3,150,000, for indirect costs to cover overhead expenses associated with running a research university.

56. Thus, upon information and belief, the second phase of funding to Columbia would have totaled $8.15 million.

57. The funding for the grant awarded to Drs. Cioffi and Petrukhin, however, is to *do the same experiments that had already been successfully conducted by SciMount*—experiments that Columbia knew had already generated conclusive positive data.

58. As stated above, SciMount provided that data to Drs. Cioffi and Petrukhin in May 2023.

59. Thus, Columbia knew that the grant it sought from the NEI was for research that had already been conducted and generated conclusive positive data.

60. Under NIH regulations, researchers are not permitted to request grants for experiments they know have already been successfully conducted.

61. NIH grants are meant to fund future research, not to reimburse past work.

62. The NIH website clearly states that the NIH cannot support a project that is already funded or pay for research that has already been done.[6]

63. Therefore, Columbia's grant application violated NIH regulations.

[6] *See* https://grants.nih.gov/grants-process/plan-to-apply/consider-your-idea-resources-and-collaborators

64. Columbia nevertheless applied for the NEI grant to conduct research it knew would be successful.

65. As a result, Columbia has a high likelihood of success in meeting the requisite milestones in the first phase of the research because this same research has been done before. Indeed, not only did SciMount give Columbia a blueprint for how to conduct the studies, but SciMount's success eliminated Columbia's uncertainty that the experiments would work.

66. Once Columbia successfully repeats SciMount's studies, following NEI panel review, Columbia would unlock funding for the second phase of funding, which at the time Columbia breached the Agreement was worth $8.15 million—$5 million in direct costs plus $3.15 million in indirect costs.

67. Only in the second phase will Drs. Cioffi and Petrukhin move on to the IND-enabling preclinical studies.

68. In or about June 2024, Columbia notified Plaintiff that Columbia received the grant for the (R)-44 studies.

69. Despite his shock that Columbia had deceived him by not disclosing the NIH grant and had deceived the NIH by applying for a grant to conduct experiments that Columbia knew had been previously successfully conducted, Dr. McLure gave Columbia the benefit of the doubt that it would correct the error.

70. As a result, Dr. McLure tried to find a solution that would allow Columbia to productively use the grant money on new and related research that would allow Plaintiff to develop (R)-44 as planned pursuant to the Agreement.

71. Plaintiff's efforts to resolve this matter amicably, however, were rebuffed by Columbia.

E. Columbia Breaches The Agreement.

72. On August 16, 2024, Dr. McLure emailed Neuman with a proposed business plan for Plaintiff to develop the (R)-44 molecule.

73. In Dr. McLure's email, dated August 16, 2024, Plaintiff also requested a three-month option extension to November 20, 2024, to meet the financing conditions, as provided in the Agreement.

74. Plaintiff's proposed business plan should have been acceptable to Columbia because it was substantially similar to the business plan SciMount submitted in connection with its agreement with Columbia, which Columbia accepted.

75. Neuman, however, responded to Dr. McLure the very same day, stating that Plaintiff's proposed business plan was unacceptable because it was substantially similar to research relating to (R)-44 proposed by Drs. Cioffi and Petrukhin. Neuman did not indicate any other dissatisfaction with the business plan.[7]

76. On information and belief, the true reason Columbia rejected Plaintiff's business plan was because it intended to use the NIH grant funding to conduct the studies related to (R)-44 itself.

77. On information and belief, had Columbia honored the Agreement, Plaintiff and Columbia would have been in direct competition to develop (R)-44—and Plaintiff was approximately two years ahead in the research.

78. Accordingly, allowing Plaintiff to proceed would have jeopardized Columbia's

[7] Columbia's conduct in this case also conflicts with CTV's mission statement "to facilitate the transfer of inventions from academic research labs to the market for the benefit of society on a local, national, and global basis." Plaintiff had established a feasible plan to complete preclinical studies within one year of raising capital and to start clinical trials in humans at that time. Conversely, Columbia's faculty members are operating under a NEI grant timeline of five years to complete preclinical studies without any specific support or expertise for planning clinical studies.

eligibility for the $8.15 million in second phase funding from NIH.

79. By the time Columbia would apply for the second phase of funding in 2026, Plaintiff would likely have completed the IND studies and begun Phase I clinical trials in humans.

80. These developments would be publicized through press releases and disclosed in regulatory filings, making it evident to the NIH that Columbia's proposed studies had already been conducted.

81. Thus, Columbia would be ineligible for continued NIH funding for duplicative research.

82. In addition, if Columbia further developed (R)-44 itself using the NEI grant funding, it could keep substantial equity in the overall investment, rather than share it with Plaintiff.

83. As a result, on information and belief, Columbia refused to consider Plaintiff's business plan in good faith as required by the Agreement because Columbia wanted to ensure it could secure the approximately $8.15 million in NIH funding and keep more of the equity in the investment.

F. Plaintiff Is Damaged Because Of Columbia's Breach.

84. Columbia's improper withdrawal from the Agreement significantly harmed Plaintiff.

85. Plaintiff dedicated over a year to planning and enabling development of (R)-44 pursuant to the Agreement to create a best-in-class drug to treat patients suffering from retinal diseases that cause blindness.

86. Moreover, Plaintiff incurred a number of expenses and losses in reasonable reliance on Columbia's promise.

87. For example, Plaintiff paid to maintain the patents, and to raise funds for asset development.

88. Plaintiff further incurred consultant fees to put non-clinical and clinical development plans in place.

89. These costs and expenses amounted to $484,293.93.

90. Finally, Plaintiff was deprived of the opportunity to develop a potentially best-in-class drug in a $20 billion market.

V. PLAINTIFF'S CLAIM FOR RELIEF

A. Breach Of Contract

91. Plaintiff repeats and realleges the above paragraphs as if fully set forth herein.

92. On November 24, 2023, Plaintiff and Columbia entered into the Agreement.

93. Plaintiff performed pursuant to the Agreement by obtaining quotes to complete the IND-enabling preclinical studies, entering into agreements with SciMount to procure the drug substance that SciMount had already produced and to use the SciMount (R)-44 data, and retaining a chemistry manufacturing and controls specialist who evaluated the SciMount data to ensure the material had been maintained properly and confirmed that it would be acceptable for use in the IND-enabling preclinical studies and the first phase of clinical studies, among other things.

94. Columbia, however, breached the Agreement by refusing to negotiate an option to license in good faith without any failure of Plaintiff to meet the conditions precedent outlined in the Agreement.

95. Columbia acted in bad faith by engaging in the actions above, including but not limited to, allowing faculty members to apply for a grant replicating SciMount's research in violation of NIH regulations, concealing from Plaintiff the scope of the preclinical work that Columbia faculty

planned to pursue if their grant was successful, and allowing Plaintiff to spend extraordinary resources, knowing that Columbia would renege on the Agreement if a more profitable opportunity presented itself.

96. As a result, Plaintiff has suffered damages in an amount to be determined at trial, including but not limited to incurring expenses in connection with the Agreement and being deprived of the opportunity to develop a potentially best-in-class drug in a $20 billion market.

B. Breach Of The Covenant Of Good Faith And Fair Dealing

97. Plaintiff repeats and realleges the above paragraphs as if fully set forth herein.

98. Within every contract there is an implied covenant of good faith and fair dealing, which is breached when a party to a contract acts in a manner that would deprive the other party of the right to receive the benefits under their agreement.

99. Here, Columbia sought to prevent performance of the Agreement and/or to withhold its benefits from Plaintiff by refusing to accept Plaintiff's business plan in bad faith.

100. On information and belief, Columbia did this because it did not want to risk losing the $774,169 Columbia had already received from the improperly awarded NIH grant funds, or the anticipated subsequent $8,150,000 second phase grant, assuming Columbia was able to successfully replicate the data already produced by SciMount and shared with Columbia, or the significant equity stake in a company that would take (R)-44 through clinical development, assuming the studies supported by the second phase grant were successful.

101. As a result, Plaintiff has suffered damages in an amount to be determined at trial.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests judgment against Columbia as follows:

(a) compensatory damages in an amount not less than $1 billion constituting Plaintiff's

lost profits plus the amount in expenses Plaintiff incurred based on Columbia's representations in the Agreement;

(b) consequential damages in an amount to be determined at trial;

(c) a determination that Columbia is liable for breach of the Agreement;

(d) a determination that Plaintiff is entitled to the right of first refusal on any future licenses that Columbia may grant with respect to the (R)-44 molecule or any similar molecule;

(e) an award of reasonable costs, including attorney's fees; and

(f) such other and further relief as the Court deems just and proper.

VII. JURY DEMAND

Plaintiff demands a trial by jury in this action.

Dated: New York, New York
May 1, 2025

MEYNER AND LANDIS LLP

By: *Catherine Pastrikos Kelly*

Catherine Pastrikos Kelly
100 Park Avenue, 16th Floor
New York, New York 10017
ckelly@meyner.com
973-602-3423
Attorneys for Plaintiff
Ermaris Bio, PBC